

# REQUEST FOR PROPOSALS: VALIDATION OF MISOPHONIA MEASUREMENT TOOLS

The Misophonia Research Fund (MRF) is dedicated to advancing a world where misophonia is scientifically understood and effective treatments are available to help anyone who is suffering. MRF is a program of The REAM Foundation, a private, U.S.-based family foundation established to help people reach their full potential through support for health and wellness, education, and arts initiatives. The MRF is now accepting applications for up to two-year research projects that seek to validate one or more tools that can be used by clinicians and researchers to identify and diagnose misophonia and assess the severity of the disorder over time.

## **Description:**

The Misophonia Research Fund intends to award 1-2 research grants in 2022 that are dedicated to validating one or more tools to identify, diagnose, and measure symptoms of misophonia. Each grant will provide up to \$200,000 USD in funding per year for up to two (2) years for a maximum, aggregate total of \$400,000 USD in total costs to support research projects led by doctoral level investigators (e.g. Ph.D., M.D., Psy.D., Au.D.) at qualifying research-based institutions.

Misophonia is a disorder of decreased tolerance to specific sounds or stimuli associated with such sounds. These stimuli, known as "triggers," are experienced as unpleasant or distressing and tend to evoke strong negative emotional, physiological, and behavioral responses that are not seen in most other people. Trigger stimuli are often repetitive and primarily, but not exclusively, include stimuli generated by another individual, especially those produced by the human body (such as chewing or sniffing). The expression of misophonic symptoms varies, as does the severity, which ranges from mild to severe impairments. For more information, visit <a href="https://www.medrxiv.org/content/10.1101/2021.04.05.21254951v2">https://www.medrxiv.org/content/10.1101/2021.04.05.21254951v2</a>.

Misophonia is under-studied and may be more common than previously realized. Some studies have found that as many as one in five individuals reports symptoms of misophonia. However, it is difficult to measure the true incidence of the disorder due to limitations in diagnosing and measuring misophonia. More specifically, the misophonia research and clinical communities use several different tools to identify the presence of misophonia and measure its severity. Not all of these tools have been psychometrically validated, nor are they based on a common, consensus definition of misophonia.

Projects proposing to validate one or more misophonia tools that may be selected for funding should display multidisciplinary collaboration, creativity, and evidence of the skills and experience necessary to develop and/or or psychometrically validate measures that can be used by clinicians and researchers to identify, diagnose, and measure the severity of misophonia. Applicants should



demonstrate awareness of the <u>consensus definition of misophonia</u>, developed and released in 2021 with support from the Misophonia Research Fund.

### **Scientific Focus**

Funded proposals may support the validation of existing misophonia measurement tools (e.g. the Amsterdam Misophonia Scale (original or revised), the S-Five, or the Duke Misophonia Questionnaire). Alternatively, proposals may support the development and validation of modified and/or new tools, with applicants expected to provide a strong justification for how new or modified assessments will necessarily improve upon existing scales and align with the priorities of the RFP, outlined below.

Proposals **should seek to validate** one or more of the following 3 types of misophonia tools, and applicants encouraged to prioritize the following features for each type of instrument:

- a **scale to screen** for the presence of misophonia symptoms
  - coverage of types of trigger stimuli, reactions to misophonic triggers, and functional impairments
  - o approximately 5 minutes to complete
  - o appropriate for completion in a variety of environments (e.g. research lab, clinician's office/waiting room)
- a **self-assessment** to assess the severity of symptoms
  - o coverage of types of trigger stimuli, reactions to misophonic triggers, influences on reactions to stimuli, and functional impairments
  - o approximately 10 minutes to complete
  - o appropriate for regular and/or repeat administration to track symptom progression and/or the impact of treatments or interventions on misophonia
- a **structured clinical interview** to confirm a diagnosis of misophonia
  - coverage of types of trigger stimuli, reactions to misophonic triggers, influences on reactions to stimuli, insight and awareness of misophonia, functional impairments, onset and course of disorder
  - o approximately 30-45 minutes for a clinician or researcher to administer
  - o appropriate detail to ensure confidence in a misophonia diagnosis, when considered in the context of other related constructs

In addition to the features listed above for each type of tool, **applicants are strongly encouraged to prioritize** the following features in all validated misophonia tools:

• Readability (e.g. 6<sup>th</sup> to 8<sup>th</sup> grade reading level) and avoidance of jargon, particularly for the screening and self-assessment instruments.



- Suitability for future translation into multiple languages, and consideration of cultural and linguistic nuances in question design and phrasing.
- Suitability for future adaptability for youth and adolescent populations.
- Validation in diverse populations across age, race, sex, ethnicity, geography, physical
  capabilities, and mental health conditions, including those that may be co-morbid with
  misophonia.
- Validation in multicultural populations to both help identify patterns in misophonia that are consistent across individuals and to help understand cultural differences in misophonia.
- Validation in both research and clinical settings.

## Depending on their expertise and team capabilities, **applicants are encouraged to consider**:

- Incorporating existing conceptual and/or diagnostic frameworks into proposed studies (e.g. <u>NIH RDoC</u> or experimental therapeutics approach) that could support the development of interventions and treatments for the disorder and position validation studies for follow-up funding from public research funders that adopt these frameworks.
- Validating multiple tools together, when practical and with appropriate customization of study design and statistical procedures for the specific type(s) of tools being validated.
- Cross-comparing multiple misophonia tools, including new and/or modified tools to existing tools currently being used for research and/or clinical purposes.

### **Priority Features of Research Teams**

- Research teams with expertise across multiple scientific and/or clinical disciplines are highly encouraged to apply.
  - Collaboration plans that describe how multidisciplinary research teams will perform the proposed research are encouraged.
- Prioritized areas of expertise include psychometrics, statistics, psychology, and audiology.
- Demonstrated prior experience validating measurement tools and/or questionnaires will be considered to be advantageous.
- Research and/or clinical knowledge and experience with individuals experiencing symptoms of misophonia will be considered to be advantageous.

## **Eligibility Criteria**

- 1. Each applicant organization must be a non-profit academic or research institution, including domestic and non-U.S. non-profit organizations, domestic and non-U.S. public/private academic universities or institutions of higher learning (including colleges, universities, medical schools, and other related academic research institutions); certain qualified governmental agencies with active biomedical research programs may also apply.
- 2. All proposed research projects must be led by a Principal Investigator (PI) who holds a doctorate (e.g., Ph.D., M.D., Psy.D., Au.D.) or related research doctorate degree. The primary



- PIs must be an independent investigator, with postdoctoral fellows eligible to serve as Co-Investigators (Co-Is) or collaborators. PIs must be selected by and identified by the applicant organization.
- 3. Institutions can submit more than one proposal, but each proposal must be led by a unique PI.
- 4. For purposes of this Request for Proposals (RFP), a "postdoctoral fellow" is an individual who has obtained a doctoral degree (Ph.D., M.D., Psy.D., Au.D. or an equivalent degree) by the grant proposal deadline and who is engaged in a temporary period of mentored research for the purpose of acquiring the professional skills needed to pursue a career path of their choosing.

# **Letter of Intent (LOI) and Application Requirements:**

All completed LOIs and applications shall be submitted through The Misophonia Research Fund's online grant portal (see below). Below is a list of required components for an application to be considered complete. **Applications shall be single spaced and formatted in Calibri 11-point font with 1-inch margins, except where provided templates apply.** 

All applicant organizations first shall submit an LOI, which will be reviewed by The Misophonia Research Fund. Selected organizations who propose relevant projects will then be invited to submit a full application, as outlined below.

- 1. **Letter of intent.** The LOI is a one-page letter briefly stating intent to apply for a grant, project title, and project aims. The LOI also requires the applicant organization's legal name; PI name, degree, position and contact information; and the organization's tax ID number (for U.S.), registered charity number, or non-U.S. country's equivalent.
  - a. LOIs are due on Friday, December 10, 2021.
  - b. LOIs should be submitted via The Misophonia Research Fund's online grants portal, which can be accessed via this link: <a href="https://tinyurl.com/MisophoniaLOI">https://tinyurl.com/MisophoniaLOI</a>. Click on the "New Applicant?" link (below the email text box) to create a new account. If you save and exit the LOI form, click on the following link to return to your LOI that is already in progress: <a href="http://tinyurl.com/continueapplication">http://tinyurl.com/continueapplication</a>.
  - c. The applicant organization will be notified by email within approximately four (4) weeks of the LOI submission deadline as to whether or not they will be invited to submit a formal proposal.
- 2. **Proposal.** A formal proposal outlining the intended project should be no more than eleven (11) pages in length (all pages over the limit will be omitted), and should be organized as follows:
  - a. <u>Cover page</u> including:
    - i. Project title (a short title identifying the project and its intended area of focus);
    - ii. The PI's name and the applicant organization's name;



- iii. Technical abstract.
- b. <u>Aims and milestones</u> (summary of what the project aims to accomplish and the major milestones the PI anticipates the project will complete in the process of meeting said project aims). Major milestones should include estimated timeframe of completion. One (1) page or less.
- c. <u>Scientific approach</u> (outline of which research methodology the PI intends to use in pursuit of the project, in addition to defining and justifying key project outcome measures). Six (6) pages or less.
  - i. Proposals must be accompanied by a brief protocol synopsis and timeline with milestones. As noted below, IRB approval will be required before initial payments are made for any project that The Misophonia Research Fund, in its sole discretion, selects for funding.
  - ii. Validation studies must include a description of inclusion and exclusion criteria of human participants and description of how misophonia will be distinguished from other similar conditions.
  - iii. Validation studies must specify a recruitment plan that will enroll participants of diverse backgrounds, including age, race, sex, ethnicity, geography, physical capabilities, and mental health conditions, including those that may be co-morbid with misophonia.
  - iv. Validation studies must include a discussion of how participants will be selected, participant diversity, necessary sample size, and control populations.
  - v. Validation studies must include a description of the environmental conditions in which assessments are administered to study participants. Standardization of environmental conditions used during assessment administration is recommended.
  - vi. Any intellectual property considerations that the proposed research may entail should be noted, including if the study would use or incorporate any existing methodology, would use or incorporate any pre-existing intellectual property of the grantee organization or a third party, or would generate a new and/or modified misophonia tool and how this tool would be made available for research and clinical practice free-of-charge to clinicians and researchers.
  - vii. If alternative plans exist that would be implemented should local conditions prevent research from proceeding as planned, please include a brief description of these arrangements.
- d. <u>Data sharing plan</u> (specifying the applicant organization's commitment to, and plan for, sharing project results, data (de-identified, where applicable), and modified or new misophonia assessments/questionnaires/measurement tools with other



institutions, researchers, clinicians, and the public for non-commercial use to advance the understanding of misophonia and to maximize scientific and patient impact, including designation of the particular data repository to which the applicant intends to upload and share such project results and data, and policies and procedures for ensuring that the applicant organization's PI and all other applicable employees and contractors will comply with and adhere to such plan). One (1) page or less.

- e. <u>Team capabilities</u> (statement outlining the research group's ability to address the research question, support the research, and manage participants, PI and potential Co-I's effort devoted to the project, and identification of any key personnel in addition to the PI). Refer to "Priority Features of Research Teams," in the Scientific Focus section, above, for more detail. One (1) page or less.
- f. References cited. One (1) page or less.
- 3. Additional documentation within the online form shall include:
  - a. Information about the applicant organization and the lead investigator it has selected, including contact information for the lead investigator and the authorized representative of the applicant organization which will receive the grant correspondence and funds.
  - b. Lay summary (succinct summary describing the project's aims, goals, any previous accomplishments, and how it will validate one or more misophonia tools). One (1) page or less.
  - c. Budget and justification (a detailed budget in USD with a narrative summary and justification for each item, including how the PI intends to spend their time on the project). Acceptable expenditures will include: salary, equipment, graduate student tuition for students fully dedicated to research, software, patient recruitment, fringe benefits, percent effort for hired personnel, project-related and/or conference travel, publication costs, and up to 15% indirect expenses to support institutional infrastructure. The maximum allowable budget is inclusive of indirect expenses. If more than one institution will be involved in the project, one shall be proposed as the applicant organization, and the other included as a sub-grantee. When a proposal includes a sub-grantee, the maximum allowable indirect rate across both grantee and sub-grantee remains 15% of the total award budget. Up to two (2) pages in length using the provided template and one (1) page in length providing narrative justification of budget items. Save the budget and justification into one single PDF document for proposal submission. For non-U.S. applicants: **Please note** grants will be made in USD, and The Misophonia Research Fund is not responsible for changes in conversion rates. Grants selected for funding will be made payable to the applicant organization. Under no circumstances will funding be paid to, or earmarked for, any individual.
  - d. Lead PI's (and Co-Is, if applicable) biosketch from the <u>NIH template</u>. Five (5) pages or less using the NIH template (all pages over limit will be omitted).



e. Institution letter of commitment stating that applicant organization will be able to support the research led by the PI.

## 4. **Non-US-based applicant organizations** must provide:

- a. A list of voting board members and officers, as well as the name of the organization's highest-ranking staff member (e.g. Chief Executive Officer).
- b. Additional organization governing documents and other documentation via a secondary questionnaire, following your proposal submission. The Foundation will make this request during proposal review. For more information, please visit <a href="https://www.ngosource.org/how-an-ed-works">https://www.ngosource.org/how-an-ed-works</a>.

# 5. <u>U.S.-based governmental organizations (excluding academic/research institutions that are public charities)</u> must provide:

- a. A full copy of the enabling statute that authorized the organization's creation.
- b. A copy of the organization's governing documents (such as articles of organization or constitution and bylaws), if applicable.
- c. Any correspondence from the IRS confirming the organization's tax status, if applicable.
- 6. Applicant organizations submitting grant requests for projects for which a postdoctoral fellow would serve as a Co-I must also submit the following regarding the selected postdoctoral fellow:
  - a. Research training information (up to one (1) page outlining the training or individual development plan and the working environment).
  - b. Mentor/sponsor letter of support.
  - c. Two (2) letters of recommendation in addition to the mentor/sponsor letter of support.
  - d. Letter from the department chair specifying that the fellow is engaged in a temporary period of mentored research for the purpose of acquiring the professional skills needed to pursue a career path of their choosing, and demonstrating a commitment of institutional resources and support for the proposed research that will further enable the successful completion of the project.

Formatting and length shall be strictly enforced by The Misophonia Research Fund. Any submissions that exceed the page limit or do not follow the aforementioned requirements shall not be considered for review.

### **Review:**

The Misophonia Research Fund will seek independent expert review for each application. All applications will be reviewed based on their scientific and technical merit, team capabilities and competencies, the potential impact of the project, its alignment with the priority features of validated misophonia tools (described above), and the realism of the cost.



# **Key Dates and Timeline:**

- 1. Friday, December 10, 2021: Letters of Intent (LOI) due via online grants portal by 11:59 p.m. Central Time.
- 2. Friday, January 7, 2022: Applicant organizations whose LOIs are selected to move to the next stage will be invited to submit full proposals.
- 3. Friday, March 11, 2022: Invited applicant organizations shall submit their full proposals via online grants portal by 11:59 p.m. Central Time.
- 4. August 2022: Applicant organizations will be notified of funding decisions.
- 5. October 2022: Grant period begins. Grantees complete administrative tasks and IRB approval process.

## **Grant Terms:**

Each funded organization will be required to co-sign and agree in writing to The Misophonia Research Fund's grant terms within thirty (30) days from receipt of notice of the award and prior to funds being released. The Misophonia Research Fund's grant terms include the following:

- 1. Signature confirming that the information provided in the grant proposal is true, complete and accurate. False or fraudulent statements may subject the funded organization to criminal, civil, or administrative penalties.
- 2. Any substantial changes to the project including activities, budget, grant period or PI require written approval from The Misophonia Research Fund before proceeding with such activities, spending, or committing any remaining funds from the grant.
  - a. Any funds not expended or committed for the purposes of the grant must be returned to The Misophonia Research Fund unless otherwise agreed by The Misophonia Research Fund in writing.
  - b. If a funded organization proposes to supplement any funds provided by The Misophonia Research Fund with funds provided by a third party, the organization must first provide notice to The Misophonia Research Fund and must ensure that the funding terms associated with any such third-party funds do not preclude sharing of data or publication of project results as contemplated in this RFP.
- 3. The funded organization must be able to receive awarded funds and allocate them exclusively toward the funded misophonia research project.
- 4. Funded organizations must agree to, and timely deliver on, the following reporting requirements in order to receive funding from The Misophonia Research Fund:
  - a. Annual submission of full written narrative and financial reports following the initial award payment, which shall, among other things, include a signed statement by an authorized representative of the funded organization and its PI confirming that the funded organization, the PI, and any other applicable employees or contractors that have worked on the project during the reporting period have



- submitted information that is true, complete, and accurate and have adhered to the Data Sharing Plan set forth in the proposal.
- b. Semi-annual submission of brief written updates describing major project highlights.
- 5. **IRB approval will be required before initial payments are made**. Evidence of protocol submission within six (6) weeks of grant funding notification may be requested. IRB approval must be maintained for the duration of the granting period.
- 6. The organization will require its designated PI to attend any annual funded scientific convenings held by The Misophonia Research Fund and will instruct its designated PI to share progress on the work funded by The Misophonia Research Fund. Expenses for attending these meetings will be covered under a separate budget by The Misophonia Research Fund.
- 7. It is a condition of any funding provided by The Misophonia Research Fund that the investigator publicly release the results of the funded project, such as on their laboratory website or a pre-print server, within twelve (12) months after the completion of the project. Furthermore, funded investigators should seek to have the results of the funded project publicly published in a peer-reviewed journal within eighteen (18) months after the completion of the project. Each publication would acknowledge The Misophonia Research Fund's role in supporting the project, in a form approved by The Misophonia Research Fund. If the investigator does not publish the results within such timeframe, The Misophonia Research Fund would have the right to make such results public.

## **Data and Intellectual Property:**

Each funded organization would own the rights in all intellectual property developed by or on behalf of that organization under The Misophonia Research Fund funding, in accordance with such organization's applicable intellectual property policies. The Misophonia Research Fund would have the right to use and to practice all such intellectual property for internal, non-commercial research purposes, and would also have the right to publicly disclose research results in press releases, announcements and otherwise (subject to the funded organization's advance approval if any such public disclosure will occur prior to publication of the applicable results).

Each funded organization must agree to share results open-access and free-of-charge, including modified or new misophonia assessments/questionnaires/measurement tools; data (de-identified, where applicable); reagents and other research tools developed under The Misophonia Research Fund funding with clinicians, researchers, and the public for non-commercial use to advance the understanding and identification of misophonia and to maximize scientific and patient impact. Sharing of data, project results, and modified or new misophonia assessments/questionnaires/measurement tools will be carried out in accordance with the approved Data Sharing Plan (as specified in the organization's project proposal).



# Funding Awarded in The Misophonia Research Fund's Discretion:

Responding to this RFP, submitting an LOI and/or submitting a full proposal does not entitle any individual or institution to receive funding from The Misophonia Research Fund. Funding, if any, would be provided in The Misophonia Research Fund's sole discretion pursuant to the terms of a written grant agreement executed by The Misophonia Research Fund and the selected grantee organization, the terms of which The Misophonia Research Fund may require to be acknowledged by the PI.

### **Contact Information:**

For all inquiries about the online process or documentation needed, please contact: info@REAMFoundation.org.

For clarification about scientific priorities or eligibility requirements, please contact: misophonia@milkeninstitute.org.

An automated email confirmation is generated upon submission of the LOI or application. If you do not receive a confirmation within 24 hours of submitting your application, please check spam filters and then contact: info@REAMFoundation.org.